SECTION 6 – 510(k) SUMMARY

OCT 1 ˇ 2007

K072468

(Premarket Notification [510(k)] Number)

1. Applicant

Spectrum Dynamics Ltd.
22 Bareket St.
North Industrial Park
POB 3033
Caesarea
30889 ISRAEL
Tel: +972-73-7374500
Fax: +972-73-7374501

Corresponding Official:

Ahava M. Stein, Consultant
A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL
Tel: +972-9-767 0002
Fax: +972-9-766 8534

2. Device Name:	D-Spect™ Cardiac Scanner System
Device trade/proprietary name:	D-Spect™ Cardiac Scanner System
Common Name:	SPECT system
Classification Name:	Emission Computed Tomography System (product code KPS, class II, classification section 892.1200).

3. Predicate Devices

The modified D-Spect™ system is substantially equivalent to the following device:

Device	Manufacturer	510(k) No.
D-Spect™ Cardiac Scanner System	Spectrum Dynamics Ltd.	K062450
ADAC AutoQuant	ADAC	K980715
ADAC JETStream Workspace	ADAC	K061029

4. Intended Use

The D-Spect™ is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The device includes display equipment, patient and equipment supports, component parts, and accessories. D-Spect™ is primarily intended for cardiac applications. D-Spect™ supports radionuclides within the energy range of 40 -170 keV.

5. Description of the Device

Spectrum Dynamics' D-Spect™ Cardiac Scanner System is a SPECT device, which is designed to perform myocardial perfusion imaging. The device is comprised of a detector head, gantry, and patient chair. Device operation is controlled from an acquisition station console. The system is supported by use of data-transfer accessories (RFID tags), which are attached to the patient's wrist and to the syringe containing the radiopharmaceutical agent, for patient and syringe positive identification. The cardiac gamma camera is designed such that there are no external moving parts that surround the patient. Detector boards rotate within the closed detector head. The special scanning geometry and detector technology, enable shorter scan times. In the modified D-Spect™ device, a Processing Station was added. The Processing Station, which is part of the display equipment, contains a software application with the Cedars Sinai Quantitative Perfusion SPECT

(QPS) and Quantitative Gated SPECT (QGS) software that enables a review and quantification of cardiac SPECT data.

6. Technological Characteristics Compared to Predicate Device

The technological characteristics, *e.g.*, overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the D-Spect™ device are substantially equivalent to the predicate devices cited above.

7. Performance Testing

The following performance testing activities were performed for the modified D-Spect™ device:

A. Software Validation

B. Electromagnetic Compatibility/ Electrical Safety Testing

Functionality tests were performed as part of the software validation testing to demonstrate that each software application functioned as per its specifications. Computer platform testing was performed by running QGS and QPS programs on computer systems with the proposed platform using gold standard Cedars- Sinai test cases.

Testing results for all validation tests demonstrated that the D-Spect™ device performs according to its specifications.

Clinical validation for the QGS and QPS programs was conducted by Cedars-Sinai Medical Center.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Spectrum Dynamics Ltd.
% Ms. Ahava Stein
Regulatory Consultant
A. Stein Regulatory Affairs Consulting
20 Hata'as St., Kfar Saba, 44425
ISRAEL

OCT 1 2007

Re: K072468
Trade/Device Name: D-Spect Cardiac Scanner System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 17, 2007
Received: September 4, 2007

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072468

Device Name: D-Spect Cardiac Scanner system

Indications for use:

D-SPECT is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The device includes display equipment, patient and equipment supports, component parts, and accessories. D-SPECT is primarily intended for cardiac applications. D-SPECT supports radionuclides within the energy range of 40 -170 keV.

Prescription Use _√_ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use___ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072468